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Proposed Registration Decision PRD2016-08

Chlorantraniliprole

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Overview

Proposed Registration Decision for Chlorantraniliprole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Rynaxypyr Technical Insecticide and DUPONT Lumivia Seed Treatment, containing the technical grade active ingredient chlorantraniliprole, for seed treatment of corn to control wireworms, cutworms and armyworm and suppress seedcorn maggot.

Chlorantraniliprole is currently registered for Rynaxypyr Technical Insecticide (Registration Number 28979) to control a variety of insect pests in several agricultural crops and turf and to control subterranean termites in various sites. For the detailed reviews of these uses see the Evaluation Report, ERC2008-03, *Chlorantraniliprole* and the Proposed Registration Decision, PRD2013-08, *Chlorantraniliprole*.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Rynaxypyr Technical Insecticide and DUPONT Lumivia Seed Treatment.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on chlorantraniliprole, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on chlorantraniliprole, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Chlorantraniliprole?

Chlorantraniliprole is an insecticide that interferes with muscle and nerve action in insects, causing paralysis and death. Chlorantraniliprole is the active ingredient in a commercial class product, DUPONT Lumivia Seed Treatment, for seed treatment of corn to manage early season insect pests. The active is currently registered to control a variety of insect pests in several agricultural crops and turf and to control subterranean termites in various sites.

Health Considerations

Can Approved Uses of Chlorantraniliprole Affect Human Health?

DUPONT Lumivia Seed Treatment, containing chlorantraniliprole, is unlikely to affect your health when used according to label directions.

Potential exposure to chlorantraniliprole may occur through the diet or when handling and applying the end-use product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using pesticide products according to label directions.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

In laboratory animals, chlorantraniliprole was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was non-irritating to the skin and minimally irritating to the eyes, and did not cause an allergic skin reaction. The end-use product, DUPONT Lumivia Seed Treatment, was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was non-irritating to the skin and eyes, and did not cause an allergic skin reaction. Based on these findings, no acute hazard labelling is required.

Registrant-supplied short-term and long-term (lifetime) animal toxicity tests were assessed for the potential of chlorantraniliprole to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, genetic damage, and various other effects. The most sensitive endpoints for risk assessment included effects on the liver and adrenal gland, occurring at very high dose levels. There was no evidence that the young were more sensitive to chlorantraniliprole than the adult animal. The risk assessment protects against these effects and other potential effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most chlorantraniliprole relative to body weight, are expected to be exposed to less than 10% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from chlorantraniliprole is not of health concern for all population subgroups. An acute dietary intake estimate is not required as no appropriate endpoint attributable to a single dose was identified.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using chlorantraniliprole on field corn (grain) are acceptable. The MRLs for this active ingredient can be found in the MRL database (see Pesticides and Pest Management portion of Health Canada's website) and no changes to the established MRLs are required based on the use of DUPONT Lumivia Seed Treatment as a seed treatment.

Occupational Risks from Handling Chlorantraniliprole

Occupational risks are not of concern when chlorantraniliprole is used according to the proposed label directions, which include protective measures.

Workers in commercial seed treatment facilities, mobile treaters and farmers planting or handling corn seed treated with DUPONT Lumivia Seed Treatment can come into direct contact with chlorantraniliprole through residues on the skin and through inhaling dust. Therefore, the label states that all workers in commercial seed treatment facilities and mobile treaters must wear

long-sleeved shirt, long pants, chemical-resistant gloves, and shoes plus socks. Seeds can only be treated in closed treatment systems. Farmers planting or handling treated seed must wear long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Chlorantraniliprole Is Introduced Into the Environment?

When used according to label directions, chlorantraniliprole is not expected to pose an unacceptable risk to the environment.

Chlorantraniliprole enters the environment by dislodging from treated seed surfaces during and after seeding when used as a seed-treatment insecticide for the control of wireworms, cutworms and armyworm and the suppression of seedcorn maggot in corn. Once in the environment, chlorantraniliprole breaks down slowly in soil and water. The major breakdown product is 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1Hpyrazol-5-yl]-6-chloro-3,8 dimethyl-4(3H)-quinazolinone (IN-EQW78), which is more persistent than chlorantraniliprole in soil and water. Chlorantraniliprole is mobile in soil and is expected to leach through the soil profile beyond 60 cm; therefore, it has the potential to reach groundwater. A Canadian field dissipation study in Prince Edward Island demonstrated that up to approximately 48% of applied chlorantraniliprole is expected to carry over to the following growing season. Chlorantraniliprole residues are not expected in the air because of chlorantraniliprole's low volatility. Chlorantraniliprole is not expected to reach surface waters in any appreciable amounts when used as a seed treatment.

When used as a seed treatment with limited environmental exposure above soil surface, chlorantraniliprole presents a negligible risk to terrestrial invertebrates such as beneficial arthropods and bees, small wild mammals, terrestrial plants, aquatic invertebrates, freshwater algae, freshwater fish, amphibians, aquatic vascular plants, marine fish and marine algae. Chlorantraniliprole poses negligible risk to soil dwelling organisms, such as earthworms. While it poses a negligible acute risk to birds, it may adversely affect avian reproduction. Therefore, hazard statements regarding the toxicity to birds are specified on the product labels.

Value Considerations

What Is the Value of DUPONT Lumivia Seed Treatment?

DUPONT Lumivia Seed Treatment provides protection to corn from early season damage by certain insect pests.

DUPONT Lumivia Seed Treatment is a commercially applied corn seed treatment for early season control of wireworms, cutworms, and armyworm (*Mythimna unipuncta*) and suppression of seedcorn maggot. DUPONT Lumivia Seed Treatment offers a new pest management option for corn growers for the listed pests, including a new mode of action for resistance management of seedcorn maggot and a new application method to control armyworm.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of DUPONT Lumivia Seed Treatment to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Workers mixing, loading and applying DUPONT Lumivia Seed Treatment in commercial seed treatment facilities and mobile treaters must use closed treatment systems only.

Environment

Although the potential of chlorantraniliprole exposure to aquatic organisms is negligible, a statement informing users of the toxicity of chlorantraniliprole to aquatic organisms is required on the product label based on its inherent toxicity. Environmental hazard and precautionary label statements are also required to inform users of potential carryover to the next season, leaching to groundwater and risk to avian reproduction.

Next Steps

Before making a final registration decision on chlorantraniliprole, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed registration decision and the Agency's response to these comments.

Other Information

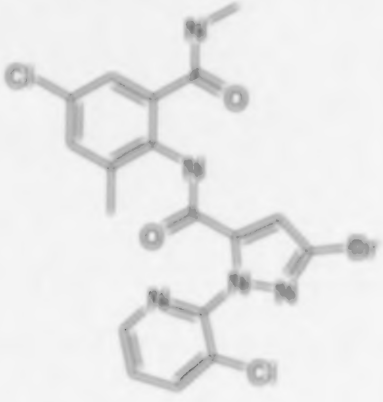
When the PMRA makes its registration decision, it will publish a Registration Decision on chlorantraniliprole (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Chlorantraniliprole

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Chlorantraniliprole
Function	Insecticide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	3-Bromo-*N*-[4-chloro-2-methyl-6-(methylcarbamoyl)phenyl]-1-(3-chloropyridin-2-yl)-1*H*-pyrazole-5-carboxamide
2. **Chemical Abstracts Service (CAS)**	3-Bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide
CAS number	500008-45-7
Molecular formula	$C_{18}H_{14}BrCl_2N_5O_2$
Molecular weight	483.15 g/mole
Structural formula	
Purity of the active ingredient	95.3 %

8.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product – Bynecyppr Technical Insecticide

Property	Result
Colour and physical state	Fine brown powder
Odour	No odour
Melting range	200–202°C
Boiling point or range	Not applicable
Density	1.5189 g/mL
Vapour pressure at 20°C	6.5×10^{-17} Pa (estimated)
Ultraviolet (UV)-visible spectrum	pH λ max (nm) neutral 290 acidic 290 basic 320
Solubility in water at 20°C	pH Solubility (mg/L) Deionized Water 1.025 4 0.972 7 0.880 9 0.971
Solubility in organic solvents at 20°C (g/100 mL)	Solvent Solubility (mg/mL) Acetone 3.4 Acetonitrile 0.71 Ethyl acetate 1.1 Dichloromethane 2.5 Dimethylformamide 120 n-Octanol 0.39 Methanol 1.7 m-Xylene 0.16 n-Hexane < 0.1 µg/mL
n-Octanol-water partition coefficient (K_{ow})	pH log K_{ow} Distilled Water 2.76 4 2.77 7 2.86 9 2.80
Dissociation constant (pK_a)	11.86
Stability (temperature, metal)	The test substance was determined to be stable at normal and elevated (54°C) temperatures, stable when in contact with the metals iron and aluminum, and stable when in contact with the metal ions from iron (III) acetate and aluminum acetate solutions.

Property	Result
Colour	White
Odour	Slight non-descript
Physical state	Viscous liquid
Formulation type	Suspension
Guarantee	600 g/L
Container material and description	High density polyethylene (HDPE)
Density	1.102–1.109 g/mL
pH of 1% dispersion in water	6–7
Oxidising or reducing action	The test substance is not a reducing agent, but is expected to react with strong oxidisers
Storage stability	Stable for one year in HDPE bottles under ambient temperature conditions
Corrosion characteristics	No corrosion to the container material was observed during one year commercial storage
Explodability	The product is not explosive

1.3 Directions for Use

DK PRO® Lumivia Seed Treatment is for application to corn seed (field, seed, pop) in commercial seed treatment facilities and mobile trailers at a rate of 0.25–0.75 mg a.i./seed for early season control of wireworms and at a rate of 0.25 mg a.i./seed for early season control of cutworms and armyworm (*Mythimna unipuncta*), and for suppression of seedcorn maggot. For wireworms, the higher rate is recommended for use in areas with high pest pressure.

1.4 Mode of Action

Chlorantraniliprole is an anthranilic diamide in the Insecticide Resistance Action Committee (IRAC) Mode of Action (MOA) Group 28. Chlorantraniliprole affects insect ryanodine receptors, causing impaired muscle regulation, paralysis and ultimately death. The active ingredient is systemic when applied as a seed treatment and acts by ingestion.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and its impurities in Rynaxypyr Technical Insecticide have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Please refer to ERC2008-03.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for chlorantraniliprole was conducted previously and is summarized in Evaluation Report ERC2008-03, *Chlorantraniliprole*. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to chlorantraniliprole.

Results of the toxicology studies conducted on laboratory animals with chlorantraniliprole can be found in ERC2008-03. Toxicology endpoints for use in human health risk assessment were established and are reported in ERC2008-03 with the exception of long-term dermal and inhalation endpoints. The latter endpoints were subsequently established and reported in the PRD2013-08.

In acute toxicity testing, the end-use product DUPONT Lumivia Seed Treatment was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was non-irritating to the skin and eyes, and was not a skin sensitizer when tested in the local lymph node assay. Results of the toxicology studies conducted on laboratory animals with DUPONT Lumivia Seed Treatment can be found in Appendix I, Table 1 of this document.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 18 September 2015, the PMRA has received two human and two domestic animal incidents involving the active ingredient chlorantraniliprole.

The human incident reports were classified as major and minor. The major incident occurred in the United States. The person in this report indicated exposure to several products containing various active ingredients including chlorantraniliprole. The circumstances that may have resulted in exposure to the products were not described in the incident. Hence, there was insufficient information to assess it. The minor incident report occurred in Canada. The person in this report experienced swollen eyes, hives and a rash following entry into a home that was treated with chlorantraniliprole.

The animal incident reports were classified as major and minor. In the major incident, an unspecified number of chickens were reported to have been exposed to a termiticide product containing the active ingredient chlorantraniliprole. One chicken was found dead. Given the timing of death as well as the low risk of the active ingredient to birds, it was considered unlikely that the death was related to the reported pesticide exposure. In the minor incident, a dog experienced abnormal behavior and lethargy after potentially walking through a spill in the yard involving a product containing chlorantraniliprole. The animal recovered shortly.

The incident report data were considered in the evaluation of the active ingredient chlorantraniliprole and did not impact the risk assessment.

3.2 Occupational and Residential Risk Assessment

3.2.1 Toxicological Endpoints

Occupational exposure to chlorantraniliprole is characterized as long-term for workers in commercial seed treatment facilities and short-term for mobile treaters and planters. Exposure is predominantly by the dermal and inhalation routes.

3.2.1.1 Dermal Absorption

A dermal absorption factor (DAF) of 7.5% was established under the previous review, see ERC2008-03, and was rounded to 8% for the risk assessment in accordance with OECD guidelines (OECD, 2011).

3.2.2 Occupational and Bystander Exposure and Risk

3.2.2.1 Commercial Worker Exposure and Risk Assessment

Corn can be treated with DUPONT Lumivia Seed Treatment in commercial seed treatment facilities or by mobile treaters, and planted using conventional seeding equipment. Worker exposure to chlorantraniliprole in commercial facilities is expected to be long-term in duration and occur primarily by the dermal and inhalation routes. For mobile treaters, exposure is expected to be short-term and by the dermal and inhalation routes. Based on the low systemic toxicity of chlorantraniliprole, no endpoints have been established for dermal and inhalation exposures of short- to intermediate-term duration (ERC2008-03). As such a risk assessment for mobile treaters is not required.

Chemical-specific data for assessing treater/applicator, bagger/sewer/stacker and cleaner exposures during pesticide handling activities were not submitted. For assessing exposure during seed treatment in commercial operations, a surrogate passive dosimetry study (AHETF, 2014) measuring the dermal and inhalation exposure of treaters/applicators, baggers/sewers/stackers and cleaners at commercial facilities treating either corn or canola with a variety of active ingredients was used. Dermal exposure was estimated by measuring residues on or in the inner whole body dosimeters, face/neck wipes, and hand washes. Inhalation exposure was estimated by measuring residues in personal air samplers fitted with an OVS tube. Three different job activities were monitored at the sites: 1) treatment of seed, including mixing, loading and operation of the seed treatment equipment; 2) packaging of treated seeds, including bagging, sewing, stacking and forklift operations; and 3) cleaning of seed treatment and seed handling equipment. The dermal and inhalation exposure values are expressed as µg/kg a.i. handled for treaters and baggers/sewers/stackers. The dermal exposure to equipment cleanout operators is provided in µg/g a.i./100 kg seed as it is not possible to determine the amount of active ingredient handled per day for cleaners. Therefore, exposure to these workers was normalized by the maximum application rate used over the treatment period.

Exposure estimates were derived for treaters/applicators applying chlorantraniliprole using closed transfer systems including closed mixing, loading, calibrating and closed treatment equipment. The exposure estimates are based on treater/applicators and cleaners wearing long-sleeved shirt, long pants, chemical-resistant gloves, and shoes plus socks. The exposure estimates are based on baggers/sewers/stackers wearing long-sleeved shirt, long pants, and shoes plus socks.

Commercial seed treating capacities were derived from the PMRA commercial default values. The default amount of corn seed treated per day (AHETF, 2013) and the average of 3000 corn seeds per kg of seed were used to estimate exposure during a typical 8 hour work day.

Dermal and inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the route-specific absorption value. Exposures were normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological end points (no observed adverse effects levels) to obtain the margin of exposure (MOE); the target MOE is 100. Inhalation and dermal risks to workers were not of concern (MOEs were above the target MOE; Appendix 1, Table 2).

3.2.2.2 Exposure and Risk Assessment for Planters of Treated Seed

Individuals have potential for exposure to chlorantraniliprole while planting and handling treated seed through dermal and inhalation routes. Exposure is expected to be short-term in duration. Based on the low systemic toxicity of chlorantraniliprole, no endpoints have been established for dermal and inhalation exposures of short- to intermediate-term duration (ERC2008-03). As such, a risk assessment for farmers planting or handling treated seed is not required.

3.2.2.3 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal.

3.3 Food Residues Exposure Assessment

3.3.1 Residues in Plant and Animal Foodstuffs

Refer to the Evaluation Report under Application Number 2008-6105 for the residues in plant and animal foodstuffs for the active ingredient chlorantraniliprole.

3.3.2 Dietary Risk Assessment

A chronic (non-cancer) dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.14), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.3.2.1 Chronic Dietary Exposure Results and Characterization

For the chronic dietary exposure assessment, MRL-level residues were used for all domestic and imported crops and livestock commodities. It was assumed that 100% of the crops were treated. The basic chronic dietary exposure from all supported chlorantraniliprole food uses (alone) for the total population, including infants and children, and all representative population subgroups ranged from 2.6% to 9.4% of the acceptable daily intake (ADI). Aggregate exposure from food and water is considered acceptable. The PMRA estimates that chronic dietary exposure to chlorantraniliprole from food and water is 3.7% (0.057859 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children of 1-2 yrs old at 9.5% (0.150348 mg/kg bw/day) of the ADI.

3.3.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified. Therefore, no acute dietary exposure assessment was conducted.

3.3.3 Aggregate Exposure and Risk

The aggregate risk for chlorantraniliprole consists of exposure from food and drinking water sources only as there are no residential uses considered for this petition.

3.4 Exposure from Drinking Water

3.4.1 Concentrations in Drinking Water

Concentrations in drinking water as a result of seed treatment uses are expected to be less than those resulting from the registered use of chlorantraniliprole as a foliar spray. Refer to ERC2008-03 for more details on drinking water concentrations of chlorantraniliprole residues as a result of foliar application.

3.5 Maximum Residue Limits

No changes to the established MRLs are required based on the use of DUPONT Lumivia Seed Treatment as a seed treatment.

4.0 Impact on the Environment

Please refer to Evaluation Report ERC2008-03, *Chlorantraniliprole* for a detailed assessment of the environmental impacts of chlorantraniliprole.

4.1 Fate and Behaviour in the Environment

The properties and environmental fate characterization of chlorantraniliprole have been previously reviewed and reported in ERC2008-03.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g., direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then

a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

The effects of chlorantraniliprole residues on terrestrial organisms have been previously reviewed and reported in ERC2008-03. Chlorantraniliprole and its transformation products did not produce significant acute adverse effects to earthworms, birds, small mammals, and terrestrial plants at relative high doses based on the results of submitted laboratory studies. Chlorantraniliprole exerts adverse reproduction effects on egg shell thickness of Bobwhite quails and live embryos of mallard ducks.

The proposed seed treatment on corn is expected to have lower environmental exposure than the registered foliar uses of chlorantraniliprole because of the lower application rates and application methods. Therefore, risks to earthworms, terrestrial plants, pollinators and arthropods are expected to be lower than the registered agricultural foliar applications. A new risk assessment for birds and mammals is conducted to characterize the risk of birds and mammals from ingested treated seeds.

To characterize the risk to birds and mammals, the likelihood of exceeding the toxic effects endpoints through feeding on treated seed was considered. The initial risk was thus characterized using the risk quotient (RQ) method: RQ is equal to estimated exposure compared to toxicity endpoint. In this risk assessment, exposure and toxicity were expressed as mg a.i./kg bw/day. The RQ is then compared to the level of concern (LOC = 1). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then the risk is further characterized by examining feeding preference, seed availability, and potential avoidance behaviour.

The exposure of birds and mammals to a pesticide through consumption of treated seed is a function of the amount of pesticide on the seed, the body weight and food ingestion rate of the animal, and the number of seeds available for consumption. As an initial conservative screening scenario, risk was characterized for generic small, medium, and large size classes of birds and wild mammals. For the screening level assessment, it was assumed that treated seed would be available for consumption over an extended time period and that 100% of the diet would consist of treated seed. Variables of feeding preference, availability of treated seed, or potential avoidance behaviour toward treated seed were not considered at the screening level.

The proposed rates in mg chlorantraniliprole per seed were converted to g a.i. per hectare and mg a.i. per kg seeds. Based on the highest label rate of 0.75 mg a.i./seed and 60.5 g a.i./ha, the highest EEC determined based on the seeding rates and application rates was 1987.5 mg a.i./kg seeds. The highest EEC was based on an Estimated Dietary Exposure (EDE) calculation using the following equations:

Estimated daily exposure (expressed as number of seeds consumed per day) = Number of seeds/g of seeds × Food Ingestion Rate (FIR expressed as g dw diet/day); and

Estimated Dietary Exposure (expressed in mg a.i./kg bw/day) = (number of seeds consumed per day × organism weight) × mg a.i./seed

The food ingestion rate (FIR) is based on allometric equations, which determine the mass of food consumed per day in dry weight, based on the body weight of the organism. The estimated EDEs for birds were 504.7, 396.5 and 115.6 mg a.i./kg bw/day for small, medium and large birds, respectively.

Screening Risk Assessment

The screening risk assessment uses acute oral LD_{50}, acute dietary 5-day LD_{50} and reproduction NOEL for bobwhite quail and acute oral LD_{50} and reproduction NOEC for rats (Appendix I, Table 3). The acute NOELs for birds and mammals were the highest treatment level based on the absence of mortality in all treatment levels. Therefore, the LD_{50}s for these endpoints were greater than the NOELs. The bird reproduction endpoint was determined based on egg shell thickness and strength. The mammalian reproduction endpoint was the highest treatment level based on the absence of adverse effects in the first and second generations.

The screening risk quotients (RQs) for birds and mammals are reported in Appendix I, Table 4.

The screening level RQs based on acute avian endpoints were <2.2, <1.8 and 0.5 for small, medium and large birds, respectively. The acute RQs for small and medium birds slightly exceeded the level of concern (LOC). This is not an acute concern as the endpoints were no effects doses. The RQs based on avian reproduction endpoint ranged from 11.4 to 50 and exceeded the LOC. The availability of seeds in the field is expected to be affected by factors such as the seeding rate (the number of seeds per unit area), whether planted seeds are buried or exposed, and whether seeds are spilled. While small birds have the highest RQ value which suggests highest risk to treated corn seeds, small birds are not likely to consume whole corn kernel because of the size of whole corn kernel. Medium birds are at higher risk than small birds because they are more likely to consume treated corn kernels than small birds. Based on the proposed seed treatment rates, a medium bird needs to consume between 2 to 4 corn kernels to be exposed to the NOEL dose. A large bird needs to consume between 14 to 40 corn kernels. When seeds are planted without drilling, a medium bird could potentially obtain the amount of treated corn kernels in less than 0.76 m^2 to reach the NOEL dose. When seeds are planted with precision drilling, a medium bird could potentially obtain the amount of treated corn kernels in 32 to 152 m^2 to reach the NOEL dose. A large bird would need a larger area (up to 1524.53m^2 with precision drilling) to acquire enough kernels to reach the NOEL dose (Appendix I, Table 5).

The screening level RQs did not exceed the LOC for any size of mammals.

Further characterization of the risk

The avian reproduction endpoint used for the screening risk assessment was NOEL of the bobwhite reproduction study for egg shell thickness and strength. The corresponding LOEL for the same reproduction study was 20.7 mg a.i./kg body weight/day. When the LOEL was used for avian reproduction risk assessment, the resulting RQs were 24.4, 19.2 and 5.6 for small, medium and large birds, respectively, and still exceeded the LOC (Appendix I, Table 6). Based on the proposed seed treatment rates, a medium bird needs to consume between 3 to 9 corn kernels to be exposed to the LOEL dose. When seeds are planted without drilling, a medium bird could potentially obtain the amount of treated corn kernels in less than 1.56 m^2 to reach the LOEL dose. When seeds are planted with precision drilling, a medium bird could potentially obtain the amount of treated corn kernels in 65 to 312 m^2 to reach the LOEL dose. A large bird could acquire enough treated kernels in 3124.53 m^2 to reach the LOEL dose. Therefore, using precision drilling to plant seeds helps prevent reproductive risk in birds.

In order to reduce the possibility that birds could consume larger quantities of treated seed, the product label and the bag of treated seeds require hazard statements for birds and a precautionary label statement to clean up spilled seeds.

4.2.2 Risks to Aquatic Organisms

The effects of chlorantraniliprole residues on aquatic organisms have been previously reviewed and reported in ERC2008-03.

Exposure of aquatic organisms through spray drift from seed treatment uses is not expected. The risk to aquatic organisms from run-off of chlorantraniliprole as a result of application on turf was determined to be negligible in ERC2008-03. Because the application rates from seed treatment uses are about 27% of the application rates from foliar uses on turf, the risk to aquatic organisms from run-off of chlorantraniliprole as a result of seed treatment uses is not expected to be of concern.

A statement informing users of the toxicity of chlorantraniliprole to aquatic organisms is required on the product label, based on its inherent toxicity.

5.0 Value

5.1 Consideration of Benefits

DUPONT Lumivia Seed Treatment provides early season protection of corn seedlings from wireworms and seedcorn maggot larvae, which live in the soil and feed directly on seed and/or seedling roots. These soil insects are important pests of corn and can have an economic impact. This product is a new pest management tool for these pests, and is a new mode of action for use against seedcorn maggot.

DUPONT Lumivia Seed Treatment also provides early season protection from larvae of cutworms and armyworm, which feed on foliage. Injury to newly-emerged seedlings may not be detected until feeding damage by these pests is already done. These foliar pests of corn are not as

widespread as wireworm and seedcorn maggot, but they can have an economic impact. DUPONT Lumivia Seed Treatment has value as a new pest management tool for these foliar pests, and provides a new application method in corn for use against armyworm.

Several other active ingredients can be used against these pests on corn. The MOA Groups for these active ingredients and the method of application in corn are listed in Appendix I, Table 7.

5.2 Effectiveness Against Pests

Pest claims were supported primarily by efficacy data from 15 field trials and 6 greenhouse trials conducted on field corn at various locations throughout the United States and Canada. The trials demonstrated that a rate of 0.25 mg a.i./seed provides early season control of cutworms and armyworm, and suppression of seedcorn maggot. The trials also demonstrated that a rate range of 0.25 to 0.75 mg a.i./seed was effective against wireworms and supported a label recommendation to use the higher rate under high pest pressure.

5.3 Non-Safety Adverse Effects

No phytotoxicity to the host crop was observed in the field and greenhouse trials as a result of treating the seed with chlorantraniliprole.

5.4 Supported Uses

The value information supports the use of DUPONT Lumivia Seed Treatment as a seed treatment for corn (field, seed, and pop) at an application rate of 0.25 – 0.75 mg a.i./seed for early season control of wireworms. An application rate of 0.25 mg a.i./seed for the early season control of cutworms and armyworm, and suppression of seedcorn maggot is also supported.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Please refer to Evaluation Report ERC2008-03, *Chlorantraniliprole*.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environment Concern* maintained in the *Canada Gazette*[5]. The list is

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[5] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including DIR99-03[7] and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Technical grade chlorantraniliprole does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

DUPONT Lumivia Seed Treatment does not contain any formulants or contaminants of human health or environmental concerns as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances and allergens known to cause anaphylactic-type reactions, or in the PMRA formulants database, Section 2.13.4 of Dir98-04 and Appendix II of Dir99-03.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for chlorantraniliprole was adequate to define the majority of toxic effects that may result from exposure. The most sensitive endpoints used for risk assessment included effects on the liver and adrenal gland, occurring at very high doses. There was no indication that the young were more sensitive to chlorantraniliprole than the adult animal. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The end-use product, DUPONT Lumivia Seed Treatment was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was non-irritating to the skin and eyes, and did not cause an allergic skin reaction.

Commercial workers in seed treatment facilities and mobile treaters and farmers planting and handling treated corn seeds are not expected to be exposed to levels of chlorantraniliprole that will result in an unacceptable risk when DUPONT Lumivia Seed Treatment is used according to label directions.

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6 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

7 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

The personal protective equipment for workers in commercial seed treatment facilities and mobile treaters is long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks. Corn seeds can only be treated in closed treatment systems. Farmers planting and handling treated seed must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks.

Bystander exposure is not of concern.

No changes to the established MRLs are required based on the use of DUPONT Lumivia Seed Treatment as a seed treatment. Please refer to ERC2008-03 and the Evaluation Report under Application Number 2008-6105 for details regarding food residue.

7.2 Environmental Risk

The use of DUPONT Lumivia Seed Treatment containing the active ingredient chlorantraniliprole is not expected to result in increased environmental exposure to terrestrial or aquatic organisms compared to registered foliar uses of chlorantraniliprole, with the exception of birds and mammals as they potentially forage on treated seeds. The risk to mammals is estimated to be negligible. However, chlorantraniliprole may affect the reproduction of birds. Hazard statements on the product label and the bag of treated seed are required to minimize the potential reproductive effects to birds.

7.3 Value

Value information demonstrated that DUPONT Lumivia Seed Treatment provides early season control of wireworms, cutworms, and armyworm (*Mythimna unipuncta*) and suppression of seedcorn maggot on corn (field, seed and pop). Chlorantraniliprole is a new mode of action for resistance management of seedcorn maggot and the product provides a new application method for the control of armyworm. DUPONT Lumivia Seed Treatment is a new pest management tool for use in corn to manage listed pests.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Rynaxypyr Technical Insecticide and DUPONT Lumivia Seed Treatment, containing the technical grade active ingredient chlorantraniliprole, for seed treatment of corn to manage early season insect pests.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

λ	*wavelength*
<	*less than*
>	*greater than*
µg	*micrograms*
a.i.	*active ingredient*
ADI	*acceptable daily intake*
AHETF	*Agricultural Handlers Exposure Task Force*
bw	*body weight*
CAS	*Chemical Abstracts Service*
CBI	*confidential business information*
cm	*centimetres*
DA	*dermal absorption*
DACO	*data code*
DAF	*dermal absorption factor*
DEEM-FCID	*Dietary Exposure Evaluation Model*
DIR	*Regulatory Directive*
dw	*dry weight*
EDE	*estimated daily exposure*
EEC	*estimated environmental exposure concentration*
FIR	*food ingestion rate*
g	*gram*
HDPE	*high density polyethylene*
IA	*Inhalation absorption*
IRAC	*Insecticide Resistance Action Committee*
IUPAC	*International Union of Pure and Applied Chemistry*
kg	*kilogram*
K_{ow}	*n-octanol-water partition coefficient*
L	*litre(s)*
LC_{50}	*lethal concentration 50%*
LD_{50}	*lethal dose 50%*
LOC	*level of concern*
LOEL	*lowest observed effect level*
m^2	*square metre*
mg	*milligram*
mL	*millilitre*
MAS	*maximum average score*
Max	*maximum*
Min	*minimum*
MIS	*maximum irritation score*
MOA	*mode of action*
MOE	*margin of exposure*
NOI	*Notice of Intent*
MRL	*maximum residue limit*
n/a	*not applicable*
nm	*nanometre*
NOAEL	*no observed adverse effect level*

NOEC	no observed effect concentration
NOEL	no observed effect level
NZW	New Zealand white
OECD	Organization for Economic Cooperation and Development
OVS	ORIBA Versatile Sampler
Pa	Pascals
pH	potential of hydrogen
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	Personal Protective Equipment
RQ	risk quotient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
UV	ultraviolet

Appendix II Tables and Figures

Table 1 Toxicity profile of the PMRA Human Health Assessment containing ethion-associated degradates

(Effects are known or assumed to occur in both sexes unless otherwise noted; in each case, sex-specific effects are separated by semi-colons.)

Study Type/Animal/PMRA #/	Study Results
Acute oral toxicity Sprague-Dawley rat PMRA #[illegible]	LD_{50} = [illegible] mg/kg bw Low toxicity
Acute dermal toxicity Sprague-Dawley rat PMRA #[illegible]	LD_{50} > [illegible] mg/kg bw Low toxicity
Acute inhalation toxicity (vapour) Sprague-Dawley rat PMRA #[illegible]	LC_{50} > [illegible] mg/L Low toxicity
Dermal irritation NZW rabbits PMRA #[illegible]	MMS = 0; MMI = 0 Non-irritating
Eye irritation NZW rabbits PMRA #[illegible]	MMS = 0; MMI = 0 Non-irritating
Dermal sensitization (local lymph node assay) CBA/J/Hsd mice PMRA #[illegible]	Non-sensitizer

Table 2 Exposure & risk estimates for workers in commercial and treatment facilities treating corn

Exposure & risk estimates for workers in commercial and treatment facilities treating corn						
Scenario (PPE)	kg a.i. handled per day	Unit Exposure (µg/kg a.i. handled)		Exposure [1] (mg/kg bw/day)		Combined MOE [2]
		Dermal	Inhalation	Dermal	Inhalation	
Tractor/applicator	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Engineer / Specialist	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Exposure & risk estimates for workers in commercial seed treatment facilities treating corn						
Stacker						
Cleanout Personnel	225 g a.i./100 kg seed	127 µg/g a.i./100 kg seed/day	24.1 µg/g a.i./100 kg seed/day	0.02858	0.06778	1640

[†] For T/As and D/S/Ss:
Exposure (mg/kg bw/day) = Unit exposure (µg/kg a.i. handled per day) × kg a.i. handled per day × DA (8%) or IA (100%)
80 kg bw × 1000 µg/mg

[‡] For Cleanout personnel, unit exposures are normalized for application rate (the highest application rate proposed was used) therefore:
Exposure (mg/kg bw/day) = Unit exposure (µg/g a.i./100 kg seed/day) × application rate (g a.i./100 kg seed) × DA (8%) or IA (100%)
80 kg bw × 1000 µg/mg

[§] Combined MOE = NOAEL (158 mg/kg bw/day) ÷ [Dermal Exposure (mg/kg bw/day) + Inhalation Exposure (mg/kg bw/day)], target MOE = 100

Table 3 Toxicity endpoints of chlorantraniliprole to birds and mammals expressed as a daily dose

Birds	Dose-based endpoint	Toxicity dose (mg a.i./kg bw/day)	Uncertainty factor	Value used for the risk assessment
Acute oral	LD_{50}	>2250*	10	>225.0
Acute dietary	LD_{50}	>1729*	10	>172.9
Reproduction	NOEL	10.1	1	10.10
Mammals	Dose-based endpoint	Toxicity dose (mg a.i./kg bw/day)	Uncertainty factor	Value used for the risk assessment
Acute oral	LD_{50}	>5000*	10	>500
Reproduction	NOEL	1199	1	1199

* These toxicity endpoints are the highest test concentrations

Table 4 Screening risk assessment for birds and mammals

	Study Endpoint (mg a.i./kg bw/day / UF)	EDE (mg a.i./kg bw/day)	RQ	LOC[1] Exceeded or not
Small bird (0.02 kg)				
Acute	225.00	504.703	2.2	Yes
Reproduction	10.10	504.703	50.0	Yes
Medium bird (0.10 kg)				
Acute	225.00	396.452	1.8	Yes
Reproduction	10.10	396.452	39.3	Yes
Large bird (1.00 kg)				
Acute	225.00	115.580	0.5	No
Reproduction	10.10	115.580	11.4	Yes
Small mammals (0.015 kg)				

	Study Endpoint (mg a.i./kg bw/day / UF)	EDE (mg a.i./kg bw/day)	RQ	LOC[1] Exceeded or not
Acute	500.00	288.424	0.6	No
Reproduction	1199.00	288.424	0.2	No
Medium mammals (0.035 kg)				
Acute	500.00	248.045	0.5	No
Reproduction	1199.00	248.045	0.2	No
Large mammals (1.00 kg)				
Acute	500.00	136.576	0.3	No
Reproduction	1199.00	136.576	0.1	No

[1] The level of concern (LOC) is one for bird and mammal risk assessment.

Table 5 Expanded reproductive risk assessment for birds

Study Endpoint (mg a.i./kg bw/day / UF)		EDE (mg a.i./kg bw/day)[a]	RQ[b]	Number of seeds needed to reach endpoint		Area required (m^2)			
						No drilling[c]		Precision drilling	
				min	max	min	max	min	max
Small bird (0.02 kg)									
Reproduction	10.10	504.703	**50.0**	0.27	0.81	0.03	0.15	6.35	30.49
Medium bird (0.10 kg)									
Reproduction	10.10	396.452	**39.3**	1.35	4.04	0.16	0.76	31.76	152.45
Large bird (1.00 kg)									
Reproduction	10.10	115.580	**11.4**	13.47	40.40	1.59	7.62	317.61	1524.53

[a] Estimated dietary exposure
[b] RQ values that exceeded the LOC are in bold.
[c] No drilling results in 100% of seeds are available for consumption.

Table 6 Further characterization of the avian reproduction risk using LOAEL

Study Endpoint (mg a.i./kg bw/day / UF)		EDE (mg a.i./kg bw/day)[a]	RQ[b]	Number of seeds needed to reach endpoint		Area required (m2)			
						No Drilling[c]		Precision drilling	
				min	max	min	max	min	max
Small bird (0.02 kg)	20.70	504.703	**24.4**	0.55	1.66	0.07	0.31	13.02	62.49
Medium bird (0.10 kg)	20.70	396.452	**19.2**	2.76	8.28	0.33	1.56	65.09	312.45
Large bird (1.00 kg)	20.70	115.580	**5.6**	27.60	82.80	3.25	15.62	650.94	3124.53

[a] Estimated dietary exposure
[b] RQ values that exceeded the LOC are in bold.
[c] No drilling results in 100% of seeds are available for consumption.

Table 7 Mode of action group and method of application for registered alternative active ingredients for each labelled pest on corn (as of 8 October 2015)

Pest	Foliar	Soil Applied	Seed Treatment
Wireworm		3A	4A, 28
Seedcorn maggot		3A	4A
Armyworm	1A, 3A, 28		
Cutworm	1A, 1B, 3A, 28	1B, 3A	4A, 28

According to the IRAC classification, the Mode of Action Groups are: 1A (carbamates), 1B (organophosphates), 3A (pyrethroids), 4A (neonicotinoids), and 28 (diamides).

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	References
	1.0 Chemistry
2392636	2009, Product Identity and Composition of End-Use Product: Chlorantraniliprole (DPX-E2Y45) 50WT.% Flowable Suspension, DACO: 3.2, 3.2.1, 3.2.2, 3.3.1 CBI
2450411	2014, Manufacturing Process Description for DuPont Lumivia Seed Treatment, DACO: 3.2.2 CBI
2404134	2007, Validation of the HPLC/UV Analytical Method for DPX-E2Y45 in DPX-E2Y45 60FS End-Use Products, DACO: 3.4,3.4.1 CBI
2404127	2007, Determination of DPX-E2Y45 in DPX-E2Y45 60FS Formulation End-Use Products, DACO: 3.4,3.4.1 CBI
2392637	2011, Chlorantraniliprole (DPX-E2Y45) FS [50%(W/W)] End-Use Product Seed Treatment: Laboratory Study of Physical and Chemical Characteristics, DACO: 3.5, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, .5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2392643	2011, Chlorantraniliprole FS [50%(W/W)] Flowable Concentrate for Seed Treatment Formulation (DPX-E2Y45) : Laboratory Study of Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14, 7.2.5 CBI
2450410	2014, Response to Clarification Request, DACO: 0.8 CBI
	2.0 Human and Animal Health
2392625	2007, Chlorantraniliprole (DPX-E2Y45) FS [50% (w/w)]: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure, DACO: 4.6.1
2392626	2007, Chlorantraniliprole (DPX-E2Y45) FS [50% (w/w)]: Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2392628	2008, Acute Inhalation Toxicity Study of Chlorantraniliprole (DPX-E2Y45) 50FS [50% (w/w)] in Albino Rats, DACO: 4.6.3
2392629	2007, Chlorantraniliprole (DPX-E2Y45) FS [50% (w/w)]: Acute Eye Irritation Study in Rabbits, DACO: 4.6.4
2392630	2007, Chlorantraniliprole (DPX-E2Y45) FS [50% (w/w)]: Acute Dermal Irritation Study in Rabbits, DACO: 4.6.5
2392631	2007, Chlorantraniliprole (DPX-E2Y45) FS [50% (w/w)]: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
1366035	2006, DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: In vivo dermal absorption in the rat, DuPont-17076, MRID: Not applicable, DACO: 5.8,IIIA 7.6.1
1366036	2006, DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: In vitro absorption in rat and human skin, DuPont-17078, MRID: Not applicable, DACO: 5.8,IIIA 7.6.2

2392624 2014, Occupational Handler Risk Assessment for Seed Treatment Workers and Handlers of Treated Seed: Chlorantraniliprole 625 G/L FS Insecticide, DACO: 5.3,5.4

2396870 2013, Agricultural Handler Exposure Task Force (AHETF) - Survey Results of Commercial and Downstream Seed Treating Facilities, DACO: 5.3,5.4

2421404 2014, Agricultural Handler Exposure Task Force Secondary Review Report of Existing Seed Treatment Study No. AH806, MRID No. 49084501, DACO: 5.3,5.4

1693480 2008, Magnitude of chlorantraniliprole residues in field corn following foliar application with Chlorantraniliprole (DPX-E2Y45) 20SC [200 g/L (w/v); 18.4% (w/w)] - Canada and U.S., 2007, 122 pages, DACO 7.4.1

3.0 Value

2392651 2014, Submission for Chlorantraniliprole 625 G/L FS Corn Seed Treatment - Canada, 2014, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3(C),10.3.3,10.4,10.5.1

2392652 Summary Table, DACO: 10.3.1

2479497 2014, Supporting Efficacy Studies for Chlorantraniliprole 625 G/L FS Corn Seed Treatment - Canada, DACO: 10.2.3.1,10.2.3.3

2479498 2014, Seedcorn Maggot Summary table, DACO: 10.3.1

2479499 2014, Wireworm Summary table, DACO: 10.3.1

2479500 2014, White grubs Summary table, DACO: 10.3.1

2545259 2015, Rationale, DACO: 10.2.3

2555758 2015, Rationale, DACO: 10.6

2573031 2015, Clarification Response, DACO: 10.6

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

Organization for Economic Cooperation and Development (OECD) (2011), Guidance Notes on Dermal Absorption: Series on Testing and Assessment No 156. (August 18, 2011)